COURAGE Chronicle

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FROM THE CHAIRMEN'S CORNER

Almost six weeks has transpired since the COURAGE Trial Kick-Off Meeting in Phoenix and, like you, the COURAGE Trial Leadership Team is anxious to get the study underway and enroll that first patient! Some of the delays we have experienced have been anticipated (finalizing the changes to the protocol and operations manual in the aftermath of the Phoenix meeting; obtaining expedited approvals from IRB's at the enrolling sites, etc.). However, some of the delays have continued to occur as a consequence of the legal and regulatory review of the contract documents, or letters of agreement (LOA's), between the pharmaceutical company sponsors and the Department of Veterans Affairs. With so much "money on the line", it is perhaps understandable--though no less frustrating—that industry is being exceedingly meticulous about contractual "dotting of the i's and crossing of the

As we discussed in Phoenix, we cannot initiate trial enrollment until each site has received IRB approval and has forwarded these signed documents to the West Haven Cooperative Studies Program Coordinating Center (CSPCC) and until the LOA's have been executed by all signatories, after which study drugs can then be shipped to the VA Central Research Pharmacy in Albuquerque and the, in turn, on to the respective enrolling sites. We are hopeful that the LOA signature process will be completed within 1 week and that we will be able to gear up for patient enrollment by the end of March (within 2-3 weeks).

In the meantime, Bob O'Rourke and I stand ready to assist you in any way possible, whether it is with advice/guidance in negotiating with your IRB's or in getting your local enrolling sites operational. We will be available by SKY-PAGER 24 hours/day, 7 days/week, and will soon be finalizing our plans for our respective Chairman's Offices in Syracuse and San Antonio to provide primary and secondary back-up coverage for all clinical and administrative inquiries relating to the COURAGE Trial.

We hope that you have maintained the same enthusiasm and commitment to the trial that was so very much in evidence in Phoenix, and that you are beginning to gear up for the screening process of trial-eligible patients during this interim. The eyes of the cardiovascular clinical research world are focused on this critically-important study, and we all remain poised to launch, in the very near future, what promises to be the definitive trial of percutaneous coronary intervention and intensive medical therapy in patients with symptomatic coronary heart disease.

We thank you again for being patient as we come down the home stretch, and we look forward with great enthusiasm to embarking on our long journey of COURAGE…

Best regards,

William E. Boden, MD
Syracuse, NY

Robert A. O'Rourke, MD
San Antonio, TX

Introduction to Canadian Co-Chairmen

Koon K. Teo, MB, BCh, PhD
Associate Professor of Medicine
University of Alberta
Division of Cardiology
Edmonton, Alberta

Merril Knudtson, M.D.
Professor of Medicine
University of Calgary School of Medicine
Director, Cardiac Catheterization Laboratory
Foothills Hospital
Calgary, Alberta

Project Coordinators Join CSP #424

Karen Potter RN, BSN has officially joined Dr. Boden at the Syracuse, New York VA Medical Center as his Project Coordinator for the COURAGE Trial on February 16th. She is currently pursuing her Master's Degree in an Adult Nurse Practitioner Program. Karen has 10 years experience as a Medical Technologist in hematology and chemistry, and has 9 years as a critical care nurse including two in the cath lab.

Sue Beasey RN, BSN has joined Dr. O'Rourke at the VA Medical Center in San Antonio, Texas very recently. Sue has 22 years experience as a nurse with a wide range of experiences including Nurse Practitioner, ICU, Burn Unit, Air Ambulance and has served 15 years in the military.

Karen and Sue will be co-project coordinators, with each responsible for half of the project sites. Any questions that study coordinators have concerning the COURAGE Trial can be directed to them.

We welcome Karen and Sue and look forward to working with both of you!

The following sites will send forms and direct questions first to this chairman's office:

***Project Coordinator*: Karen Potter, RN,BSN**

Address: Upstate New York VA Healthcare Network
Cardiovascular Clinical Trials RM 802
800 Irving Avenue
Syracuse, New York 13210 – 2799
Phone: (315) 476-7461 Ext. 2806
FAX: (315) 477-4579
E-mail: karen.potter@med.va.gov

All Canadian Sites

And the following **VA Sites:**

- Ann Arbor
- Durham
- Iowa City/University of Iowa
- New York
- San Antonio
- Seattle

The following sites will send forms and direct questions first to this chairman's office:

***Project Coordinator*: Sue Beasey, RN,BSN**

Address: Audie Murphy VAMC
Cardiology
7400 Merton Minter Blvd.
San Antonio, Texas 78284
Phone: (210) 617-5300 Ext. 4 408
FAX: (210) 567-4687
E-mail:

All U.S. (Non VA) Sites

And the following **VA Sites:**

- Albuquerque
- Atlanta
- Houston
- Lexington
- Little Rock
- Nashville/Vanderbilt University

Economic Core Lab

Kate & Joy

COURAGE Chronicle

NOTES FROM WEST HAVEN

Randomization Calls

When a patient is ready to be randomized, a call must be made to the Coordinating Center to confirm the patient's eligibility and to receive the treatment assignment. If unable to contact the Center either in an emergency situation or if the backup envelope system is used, then the Coordinating Center must be informed as soon as possible after the randomization, by the next working day.

Research Coordinators:

TOLL FREE : (888) 803-5560

Ray Kilstrom 203-932-5711 Ext. 3793

Liz Petrokaitis 203-932-5711 Ext. 3761

FTS: 700-428-EXT (for VA Hospitals)

The 800 line does not roll over to the main hospital number. If you get the answering machine and need to speak to someone directly, please call one of the coordinators at the extensions listed above.

Alternate contacts:

Pamela Hartigan Ext. 3773

Tenya Marie Economou Ext. 3760

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A revised operations manual, case report forms, randomization envelopes, mailing labels and a revised Scheduling System floppy disk will be sent to each center in about two weeks.

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IRB Reminder

A revised *Protocol* incorporating all of the changes agreed to at the kickoff meeting has been mailed to each center. As a reminder, we need a copy of the minutes of the IRB meeting (and R&D for VA's) or a memo approving the study – documentation that the protocol and changes have been approved by your institution. This needs to be dated after February 1. Please send a copy to the West Haven Data Coordinating Center and the Pharmacy Coordinating Center in Albuquerque.

Documentation of IRB approval must be provided before any study drugs can be shipped to the participating sites.

Scheduling System Update 3/1/1999

The Scheduling System has been revised based on the suggestions we received at the Study Start-Up Meeting in January. Two new fields have been added to the *Appointments and Patient Information* screen. A *Note* field has been added to the upper part of the screen. This will hold up to 100 characters of data depending on the number of spaces that you include in the information. You may use this field to enter an alternate address and telephone number for a patient. This field is included in both the *Patient Schedule Report* and the *All Patients Summary Report*.

The *Required Forms* field in the lower part of the screen is much smaller and a new field, the *Clinic Name*, has been added. The clinic name defaults to *Cardiology Clinic*, but you may overwrite this with another name (20 characters maximum). This field is included in the *Reminder Letters Report* and in the *All Patients Summary Report*.

Other revisions include the form names and numbers and the visits where each form is required (reflecting the revisions in the *Schedule of Evaluations* in the Protocol), and the original study logo in the *Reminder Letters Report* has been replaced with the Scheduling System Main Menu logo.

We hope you will find these revisions helpful. A revised addendum to the User's Guide, which will include these changes, will be mailed to you along with the revised Scheduling System on a floppy disk in about two weeks. Instructions for loading these revised files on the pentablet will also be included.